AMENDMENTS TO THE CLAIMS

The present amendment cancels claim 11 and adds claims 33-45. According to 37 C.F.R. § 1.121(c), after entry of the present amendment, the following claims are in the case:

1. (Original) An isolated nucleic acid segment comprising at least a first isolated coding region that encodes a first peptide of between 18 and about 24 amino acids in length that comprises an amino acid sequence that is at least about 88% identical to the amino acid sequence of SEQ ID NO:2.

2. (Original) The nucleic acid segment of claim 1, wherein said at least a first isolated coding region encodes a first peptide that comprises an amino acid sequence that is at least about 94% identical to the amino acid sequence of SEQ ID NO:2.

3. (Original) The nucleic acid segment of claim 2, wherein said at least a first isolated coding region encodes a first peptide comprising the amino acid sequence of SEQ ID NO:2.

4. (Original) The nucleic acid segment of claim 3, wherein said at least a first isolated coding region encodes a first peptide that has the amino acid sequence of SEQ ID NO:2.

5. (Original) The nucleic acid segment of claim 3, wherein said at least a first isolated coding region comprises the nucleotide sequence of SEQ ID NO:1.

6. (Original) The nucleic acid segment of claim 5, wherein said at least a first isolated coding region has the nucleotide sequence of SEQ ID NO:1.

7. (Original) The nucleic acid segment of claim 1, wherein said at least a first isolated coding region is positioned under the control of a promoter.

8. (Original) The nucleic acid segment of claim 1, wherein said nucleic acid segment further comprises at least a second isolated coding region that encodes a second protein, polypeptide or peptide.

9. (Original) The nucleic acid segment of claim 8, wherein said at least a first isolated coding region is operatively attached, in frame, to said at least a second isolated coding region and wherein said nucleic acid segment encodes a fusion protein in which said first peptide is linked to said second protein, polypeptide or peptide.

10. (Original) The nucleic acid segment of claim 8, wherein said at least a second isolated coding region encodes a second, distinct *Coccidioides spp.* protein, polypeptide or peptide.

Claim 11 canceled

12. (Original) The nucleic acid segment of claim 8, wherein said at least a second isolated coding region encodes an adjuvant protein, polypeptide or peptide.

13. (Original) The nucleic acid segment of claim 1, further defined as a recombinant vector.

14. (Original) The nucleic acid segment of claim 1, comprised within a recombinant host cell.

15. (Original) The nucleic acid segment of claim 1, comprised within a pharmaceutically acceptable carrier or diluent.

16. (Original) A recombinant vector that comprises at least a first isolated nucleic acid segment in accordance with claim 1.

17. (Original) A recombinant host cell that comprises at least a first isolated nucleic acid segment in accordance with claim 1.

18. (Original) The recombinant host cell of claim 17, wherein said host cell further comprises at least a second isolated coding region that encodes a second, distinct *Coccidioides spp.* protein, polypeptide or peptide.

19. (Original) The recombinant host cell of claim 17, wherein said host cell is a prokaryotic host cell.

20. (Original) The recombinant host cell of claim 17, wherein said host cell is a yeast host cell or a mammalian host cell.

21. (Original) A composition comprising at least a first isolated nucleic acid segment in accordance with claim 1.

22. (Original) The composition of claim 21, wherein said composition further comprises at least second isolated coding region that encodes a second, distinct *Coccidioides spp.* protein, polypeptide or peptide.

23. (Original) The composition of claim 21, wherein said composition comprises a pharmaceutically acceptable carrier or diluent.

24. (Original) The composition of claim 21, wherein said composition further comprises at least a first adjuvant.

25. (Original) A vaccine formulation comprising, in a pharmaceutically acceptable form, an immunologically effective amount of at least a first isolated nucleic acid segment in accordance with claim 1.

Claims 26-32 canceled

33. (New) An isolated nucleic acid molecule comprising an isolated coding region that encodes a peptide having the amino acid sequence of SEQ ID NO:2.

34. (New) The nucleic acid molecule of claim 33, wherein said isolated coding region has the nucleotide sequence of SEQ ID NO:1.

35. (New) The nucleic acid molecule of claim 33, wherein said isolated coding region is positioned under the control of a promoter.

36. (New) The nucleic acid molecule of claim 33, further defined as a recombinant vector.

37. (New) The nucleic acid molecule of claim 33, comprised within a recombinant host cell.

38. (New) The nucleic acid molecule of claim 33, comprised within a pharmaceutically acceptable carrier or diluent.

39. (New) A recombinant vector that comprises an isolated nucleic acid molecule in accordance with claim 33.

40. (New) A recombinant host cell that comprises an isolated nucleic acid molecule in accordance with claim 33.

41. (New) The recombinant host cell of claim 40, wherein said host cell is a prokaryotic host cell.

42. (New) The recombinant host cell of claim 40, wherein said host cell is a yeast host cell or a mammalian host cell.

43. (New) A composition comprising an isolated nucleic acid molecule in accordance with claim 33.

44. (New) The composition of claim 43, wherein said composition comprises a pharmaceutically acceptable carrier or diluent.

45. (New) The composition of claim 43, wherein said composition further comprises at least a first adjuvant.

RESPONSE

I. Status of the Claims

Prior to the Action, claims 1-25 were pending and have been examined. Presently, no claims have been amended. Claim 11 has been canceled without prejudice or disclaimer. Claims 33-45 have been added, which are unified with the examined claims and supported by the claims and specification.

Claims 1-10, 12-25 and 33-45 are therefore in the case. According to 37 C.F.R. § 1.121(c), a copy of the pending claims is provided in the amendment section.

II. Support for the Claims

Support for the new claims exist throughout the specification and claims of the original and parent applications, with exemplary support in the pending claims as follows.

New claim 33 has particular support in claims 1 and 4, and throughout the specification.

Dependent claims 34 and 35 have particular support in claims 6 and 7, respectively, and throughout the specification.

Dependent claims 36, 37, and 38 have particular support in claims 13, 14 and 15, respectively, and throughout the specification.

New vector claim 39 has particular support in claims 16, 1 and 4, and throughout the specification.

New host cell claim 40 has particular support in claims 17, 1 and 4, and throughout the specification.

Dependent claims 41 and 42 have particular support in claims 19 and 20, respectively, and throughout the specification.

New composition claim 43 has particular support in claims 21, 1 and 4, and throughout the specification.

Finally, dependent claims 44 and 45 have particular support in claims 23 and 24, respectively, and throughout the specification.

It will therefore be understood that no new matter is included within the pending claims.

III. Drawings

The Action at page 2, Item 3 objects to the drawings and requests a proposed drawing correction or corrected drawings. Applicants include corrected drawings with the present response.

IV. Applicants Telephone Interview Summary

After review of the Action, a number of telephone calls and interviews were held between Applicants' representative, Shelley Fussey, and Examiner Baskar of the Office, including a detailed telephone interview on April 19, 2004. Applicants appreciate the examiners' time and the guidance provided.

Applicants' representative disagreed with the rejections of record, but indicated that Applicants were considering emphasizing SEQ ID NO:2 in the claims and filing a continuing application to further examination. Examiner Baskar indicated that this strategy would overcome all rejections of record, and that any remaining matters could indeed be addressed in a continuing application. Therefore, although agreement was not reached on the original claims, the scope of claims that could be allowed in the next communication was agreed.

Applicants maintain their traversal of the rejections of record as applied to all pending claims and respectfully request reconsideration thereof in light of the present response. However, in the interests of efficient progress to allowance, the agreement reached regarding

patentable claims is implemented by entry of the new claims presented herein. The present actions are being taken without acquiescing with any of the outstanding rejections, but simply in order to progress the application to issue as timely as possible, particularly in light of patent term considerations. Should Examiner Baskar identify any informalities in the claims, Applicants respectfully request a telephone call to the undersigned Applicants' representative so that any remaining issues can be efficiently resolved to secure allowance.

V. Rejection of Claims 1-2 and 7-25 Under 35 U.S.C. § 112, First Paragraph

Claims 1-2 and 7-25 are first rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enabling support in the specification. Although Applicants respectfully traverse, the Action's concerns are addressed.

The Action's concern exists with the % identity language included in the claims (Action at page 3). Given the length also recited in the claims, it is clear that the rejected claims cover peptides with only minimal amino acid changes from SEQ ID NO:2. Given the very moderate scope of the claims, the detailed teaching in the specification and the high level of technical skill in the art, the Action has not met the burden required to support a *prima facie* rejection. The Federal Circuit's predecessor court held:

> "As a matter of patent office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.
>
> *In re Marzocchi & Horton*, 169 USPQ 367 (CCPA 1971), emphasis as in original.

The Action does not present sufficient reasons to doubt the objective truth of the enabling support for claims 1-2 and 7-25. The rejection is therefore improper and should be withdrawn.

Importantly, the Action clearly confuses the issues of "teaching" in the specification and the presence of working examples, stating that the specification "provides no working examples demonstrating (i.e., guidance) enablement for any fragments/variants" (Action at page 4). Thus, "working examples demonstrating" and "guidance" are improperly treated as the same. The enablement requirement of 35 U.S.C. § 112, first paragraph is for the specification to teach, not demonstrate, one of ordinary skill in the art how to make and use the claimed invention without undue experimentation in light of the disclosure. The present specification clearly meets this teaching requirement, with the presence of working examples supplemented by detailed teaching and guidance regarding the few variations included within the scope of the claims.

In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988), cited in the Action at pages 3-4, supports Applicants' position on enablement. In *Wands*, the Office took the position that the applicant failed to demonstrate that the disclosed biological processes could reproducibly result in a useful biological product (hybridomas) within the scope of the claims. In its decision overturning that position, the Federal Circuit emphasized that the need for some experimentation requiring, *e.g.*, production of the biological material followed by routine screening, was not a basis for a finding of non-enablement. *Wands* at 1406-7.

The same is true in the present case. The specification teaches the production of nucleic acid segments encoding peptides based upon SEQ ID NO:2 and a range of screening assays suitable for testing the resulting peptides. Thus, the present specification enables the scope of the claims in the manner required by *Wands*, the case law relied upon in the Action.

Although the Action cites Rudinger, 1976; Burgess *et al.*, 1990; Lazar *et al.*, 1988; and Jobling & Holmes, 1991 in an attempt to support the rejection (Action at pages 4-5), none of these references are effective to cast doubt on the enabling teaching in the specification, to contradict controlling case law or to otherwise support the rejection. In addition, it is noted that

the references relied upon are from 1976, 1990, 1988 and 1991, the most recent of which is still ten years before the priority date of the present application, and that the level of technical skill in the art has advanced during this time.

The Action's conclusions that enabling support requires "a specific demonstration of efficacy on a case-by-case basis", absent which "the invention would require undue experimentation to practice as claimed" (Action at page 5) highlights the legal errors in the Action's position. The Federal Circuit clearly held that a specific demonstration of each species within the scope of the claims is not required, and that the need for some experimentation is not a basis for a finding of non-enablement. *In re Wands, supra.* Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976).

To the extent that they are relevant, the four references cited by the Action actually support Applicants' position on enablement by showing that, even many years ago, those of ordinary skill in the art could make changes in amino acid sequences and routinely test the products to determine whether the change has an effect on function or not. Such routine screening is not a basis for a finding of non-enablement because, as the Federal Circuit summarized, "practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one 'experiment' is not simply screening of one hybridoma but rather is entire attempt to make desired antibody". *Wands* at 1400.

Thus, claims 1-2 and 7-25 are fully enabled by the specification and the rejection is overcome. As shown by claims 3-6, and as agreed during the telephone interview, new claims 33-45 are even further removed from this ground of rejection.

The § 112, first paragraph rejection is therefore overcome and should be withdrawn.

VI. Rejection of Claims 1-25 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-25 are next rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. Although Applicants respectfully traverse, the Action's concerns are addressed.

The Action at page 6, Item 9, questions the clarity of claims 1, 2, 10, 11, 18 and 22, alleging that the terms "between 18 and about 24 amino acids", "at least about 88%", "at least about 94%" and "distinct" render the claims indefinite. The rejection is *prima facie* inapplicable to claims 3-6, as the particular wording of these claims means that the complained of terms are "read out of" these claims. The rejection as applied to the remaining claims is unfounded and overcome.

Claim 1 is allegedly vague in reciting "between 18 and about 24 amino acids", the Action at page 6 questioning what Applicants intend to mean. Applicants are using the phrase "between 18 and about 24 amino acids" according to its ordinary and customary meaning and the specification does not use this term in a manner other than its ordinary meaning. Thus, there is no special definition attached to this phrase, which simply means "between 18 and about 24 amino acids", as would be understood by those of ordinary skill in the art.

Next, claims 1 and 2 are allegedly vague in reciting "at least about 88%" and "at least about 94%", the Action at page 6 again questioning what Applicants intends. Applicants are again using the phrases "at least about 88%" and "at least about 94%" according to their ordinary and customary meaning, which would be clearly understood in the context of the specification and claims by those of ordinary skill in the art. For example, with reference to the peptide of SEQ ID NO:2, a peptide of 18 amino acids in length, one amino acid change would result in a peptide with 17 amino acids the same. Numerically, this is 94.4% identity, which is clearly conveyed by the "at least about 94% identical" language in the claims.

Should the Action intend to question the use of the terms "about" and "at least about" *per se*, there is considerable case law establishing that the use of such terms is completely acceptable. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 303, 316 (Fed. Cir. 1983). The term "about" is permissible in patent claims. *Ex parte Sheldon*, 92 USPQ 374 (BPAI 1950). "The descriptive word 'about' is not indefinite as argued by the examiner. Its meaning ... is clear but flexible and is deemed to be similar in meaning to term such as 'approximately' or 'nearly.'" *Ex parte Eastwood*, 163 USPQ 316 (BPAI 1968). Claims using "about" with a numerical figure are not indefinite. *BJ Services Co. vs. Halliburton Energy Services Co.*, 338 F.3d 1368 (Fed. Cir., 2003). The fact that some claim language is not precise does not automatically render a claim indefinite. *BJ Services vs. Halliburton, supra*, quoting *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 221 USPQ 568 (Fed. Cir. 1984).

As to pending claims 10, 18 and 22, the Action questions the term "distinct", alleging that the specification does not define this term. Firstly, one of ordinary skill in the art would clearly understand the term "distinct", as used in the claims, without reference to the specification. The "first" peptide of the claims is based upon SEQ ID NO:2, as defined in claim 1. Any "second, distinct" *Coccidioides spp.* protein, polypeptide or peptide, as in claim 10, would be readily understood to be a "second" protein, polypeptide or peptide "distinct" from the first peptide, *i.e.*, a second protein, polypeptide or peptide "in addition to" the first peptide. In any event, this term is clearly defined in the specification, both with a straightforward definition of what the term means, followed by an explanation distinguishing the term "distinct" from further copies of the first peptide:

> "A 'second, distinct' *Coccidioides spp.* protein, polypeptide or peptide means a protein, polypeptide or peptide 'distinct from', *i.e.*, in addition to, the peptide encoded by the first isolated coding region. Alternatively, the at least a second isolated coding region may encode further copies of the first peptide. Such expression constructs may be used to prepare a plurality of isolated peptides, which can be operatively assembled into a multiple antigen peptide (MAP) construct."
>
> Specification at page 7, lines 8-14.

Thus, the original claims are sufficiently definite and the rejections are overcome. As agreed during the interview, new claims 33-45 are even further removed from these grounds of rejection.

The § 112, second paragraph rejections are therefore overcome and should be withdrawn.

VII. First Rejection of Claims 1-25 Under 35 U.S.C. § 102(b)

Next, claims 1-25 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Dugger *et al.*, 1996 ("Dugger"). Although Applicants respectfully traverse, the Action's concerns are addressed.

A rejection on the grounds of anticipation requires the disclosure, in a single reference, of every element of a claimed invention and requires that each and every facet of the claimed invention be identified in the applied reference. *Ex parte Levy*, 17 USPQ2d 1461 (B.P.A.I. 1990); *Minnesota Mining & Mfg. v. Johnson & Johnson Orthopaedics, Inc.*, 24 USPQ2d 1321 (Fed. Cir. 1992).

The claimed invention, in the present case, is directed to isolated nucleic acid segments, and related vectors and host cells, in which an isolated coding region encodes a peptide of between 18 and about 24 amino acids in length with a defined amino acid sequence based on SEQ ID NO:2.

Dugger concerns a full length protein of 194 amino acids. It does not teach or suggest any isolated peptides of between 18 and about 24 amino acids in length, let alone those based upon SEQ ID NO:2. The Action at page 7 was therefore in error in proposing that Dugger discloses a coding region that encodes "a peptide" that reads on claims 1-8. The isolated coding regions of the claimed invention encode peptides of only 18 to about 24 amino acids in length, whereas the coding region of Dugger encodes a protein of 194 amino acids in length.

This fundamental difference means that Dugger cannot anticipate the present claims as an anticipation rejection requires "among other things, identity of invention". *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983). Not only is there no identity of invention between Dugger and the present claims, but the claimed invention represents a surprising and unexpected advance over Dugger, which is implicitly acknowledged by the absence of § 103 rejections from the Action.

Indeed, and as confirmed during the telephone interviews, the Action's concerns over Dugger rest largely with second isolated coding regions that encode "a second, distinct polypeptide or peptide sequence from SEQ ID NO:4", as in claim 11. Original claim 11 was clearly novel and non-obvious over Dugger, by requiring a first isolated coding region that encodes a peptide of between 18 and about 24 amino acids in length, and a second isolated coding region that encodes a second, distinct polypeptide or peptide sequence from SEQ ID NO:4. The Action at page 7 is in error in stating that Dugger teaches second isolated coding regions encoding second, distinct proteins, polypeptides or peptides, as only a single coding region encoding a protein of 194 amino acids in length is disclosed in Dugger. Nonetheless, Applicants have taken the precaution of canceling claim 11.

For the record, Applicants also point out that this rejection was improperly applied to a number of pending claims. For example, Dugger does not disclose fusion proteins or a pharmaceutical or vaccine formulation of the nucleic acid.

Returning to the main issue, and as agreed in the interview, the pending claims are clearly novel and non-obvious over Dugger and the rejection is overcome. As further agreed, new claims 33-45 are even further removed from the anticipation rejection over Dugger.

The first § 102(b) rejection is therefore overcome and should be withdrawn.

VIII. Second Rejection of Claims 1-25 Under 35 U.S.C. § 102(b)

Claims 1-25 are further rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Zhu *et al.*, 1996 ("Zhu"). Although Applicants respectfully traverse, the Action's concerns are addressed.

Zhu concerns the same full length protein of 194 amino acids as in Dugger. The claimed invention is therefore novel over Zhu for the same reasons as set forth above regarding Dugger. Zhu does not teach or suggest any isolated peptides of between 18 and about 24 amino acids in length, or any isolated peptide of about 88% or about 94% identity to SEQ ID NO:2. Zhu thus does not read on claims 1-8, and the claimed invention is novel over Zhu. *Ex parte Levy, supra; Minnesota Mining & Mfg. v. Johnson & Johnson Orthopaedics, Inc., supra; Kalman v. Kimberly-Clark Corp., supra.*

It was confirmed during the telephone interviews that the Action's concerns over Zhu were also due to a possible perceived overlap with second, distinct polypeptides or peptides from SEQ ID NO:4, as in claim 11. Such concerns are unfounded, as set forth above, and claim 11 is novel over Zhu by requiring first and second isolated coding regions, whereas Zhu discloses only a single coding region encoding a protein of 194 amino acids. Nonetheless, claim 11 is no longer pending.

Applicants also point out for the record that the rejection over Zhu was improperly applied to a number of pending claims, *e.g.*, as Zhu does not disclose a pharmaceutical or vaccine formulation of the nucleic acid.

As agreed during the interview, the pending claims are clearly novel and non-obvious over Zhu and the rejection is overcome. As further agreed, new claims 33-45 are even further removed from the anticipation rejection over Zhu.

The second § 102(b) rejection is therefore overcome and should be withdrawn.

IX. Third Rejection of Claims 1-25 Under 35 U.S.C. § 102(b)

Finally, claims 1-25 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jiang *et al.*, *Infect. Immun.*, 67:5848, 1999 ("Jiang"). Although Applicants respectfully traverse, the Action's concerns are addressed.

The Action cites Jiang as disclosing the same full length protein, of 194 amino acids, as in Dugger and Zhu and relies on the same reasoning for alleged anticipation as set forth above (Action at page 9). The claimed invention is novel over Jiang for the same reasons as detailed above regarding Dugger and Zhu. Jiang does not teach or suggest any isolated peptides of between 18 and about 24 amino acids in length, or any isolated peptide of about 88% or about 94% identity to SEQ ID NO:2. Jiang therefore does not anticipate the claimed invention. *Ex parte Levy, supra; Minnesota Mining & Mfg. v. Johnson & Johnson Orthopaedics, Inc., supra; Kalman v. Kimberly-Clark Corp., supra.*

Applicants also maintain, for the record, that the Action has not clearly established that Jiang discloses a fusion protein. Therefore, the rejection over Jiang was improperly applied to a number of pending claims.

In summary, as agreed during the interview, the pending claims are clearly novel and non-obvious over Jiang and the rejection is overcome. As further agreed, new claims 33-45 are even further removed from the anticipation rejection over Jiang.

The third § 102(b) rejection is therefore overcome and should be withdrawn.

X. Formal Issues

The Action cited Jiang *et al.*, *Infect. Immun.*, 67:5848, 1999, which was not submitted by the Applicants in an Information Disclosure Statement (IDS), in a rejection without providing a copy to the Applicants. Under the current rules, this renders the Official Action improper. Nonetheless, in the interests of efficiency, Applicants elected not to contest the Action on such procedural grounds.

Applicants note that the cited references Dugger, Zhu and Jiang, and their sequences, have not been listed on a Form PTO-892. Applicants therefore respectfully request that a copy of a Form PTO-892 listing all references cited by the Office be provided with the Notice of Allowance or next communication for Applicants' records.

XI. Conclusion

This is a complete response to the referenced Official Action. In conclusion, Applicants submit that, in light of the foregoing remarks and enclosed documents, the present case is in condition for allowance and such favorable action is respectfully requested.

Should Examiner Baskar have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.

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